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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,279	08/01/2003	Stephanie K. Clendennen	EP03-008C	3830
23500	7590	04/18/2006	EXAMINER COLLINS, CYNTHIA E	
PATENT DEPT EXELIXIS, INC. 170 HARBOR WAY P.O. BOX 511 SOUTH SAN FRANCISCO, CA 94083-0511			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,279	CLENDENNEN ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-22 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-15, 17-22 and 26, and SEQ ID NO:1, in the reply filed on February 3, 2006 is acknowledged. Claims 16 and 23-25 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 17-22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid comprising a PRU promoter that comprises a nucleotide sequence comprising SEQ ID NO:1 or a fragment or variant thereof that exhibits seed-associated promoter activity. The claims are also drawn to a plant expression vector, plant cell and plant comprising said isolated nucleic acid.

The specification describes an isolated nucleic acid obtained from cherry (*Prunus avium*) comprising a promoter that comprises a nucleotide sequence comprising SEQ ID NO:1 that exhibits seed-associated promoter activity, and an isolated nucleic acid obtained from cherry (*Prunus avium*) comprising a promoter that comprises a nucleotide

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sequence comprising the reverse complement of SEQ ID NO:1 (set forth in SEQ ID NO:6) that exhibits seed-associated promoter activity (sequence listing; page 5; pages 16-24). The specification does not describe sequences that are fragments or variants of SEQ ID NO:1 or its reverse complement that exhibit seed-associated promoter activity.

The Federal Circuit has recently clarified the application of the written description requirement to polynucleotides. The court stated that “A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and uncharacterized fragments or variants of SEQ ID NO:1 and its reverse complement that exhibit seed-associated promoter activity, nor the structural features unique to the genus.

Claims 1-15, 17-22 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising a PRU promoter that comprises a nucleotide sequence comprising SEQ ID NO:1 or its reverse complement (SEQ ID NO:6), does not reasonably provide enablement for fragments or variants of SEQ ID NO:1 and its reverse complement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to an isolated nucleic acid comprising a PRU promoter that comprises a nucleotide sequence comprising SEQ ID NO:1 or a fragment or variant thereof that exhibits seed-associated promoter activity. The claims are also drawn to a plant expression vector, plant cell and plant comprising said isolated nucleic acid.

The specification discloses an isolated nucleic acid obtained from cherry (*Prunus avium*) comprising a promoter that comprises a nucleotide sequence comprising SEQ ID NO:1 that exhibits seed-associated promoter activity, and an isolated nucleic acid obtained from cherry (*Prunus avium*) comprising a promoter that comprises a nucleotide sequence comprising the reverse complement of SEQ ID NO:1 (set forth in SEQ ID NO:6) that exhibits seed-associated promoter activity (sequence listing; page 5; pages 16-24). The specification does not disclose sequences that are fragments or variants of SEQ ID NO:1 or its reverse complement that exhibit seed-associated promoter activity.

The full scope of the claimed invention is not enabled because it is unpredictable whether fragments or sequence variants of SEQ ID NO:1 or its reverse complement would function as a promoter, or as a seed-associated promoter, because basal and tissue-specific promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in a particular arrangement in the polynucleotide, which nucleotides and motifs may not be present or properly arranged in fragments or sequence variants of SEQ ID NO:1. or its reverse complement

Fragments or sequence variants of SEQ ID NO:1 or its reverse complement may lack key nucleotides required for basal promoter function. See, for example, Kim Y et al.

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(A 20 nucleotide upstream element is essential for the nopaline synthase (*nos*) promoter activity. Plant Mol Biol. 1994 Jan;24(1):105-17), who teach that various point mutations in the *nos* promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

Fragments or sequence variants of SEQ ID NO:1 or its reverse complement may also lack key nucleotide motifs required for tissue-specific promoter function. See, for example, de Pater S et al. (A 22-bp fragment of the pea lectin promoter containing essential TGAC-like motifs confers seed-specific gene expression. Plant Cell. 1993 Aug;5(8):877-86), who teach that a 22 bp region located from nucleotide -56 to nucleotide -35 of the pea lectin promoter sequence contains three overlapping TGAC-like motifs that function to confer seed-associated gene expression to the promoter (page 877 abstract; page 879 Figure 2).

Fragments or sequence variants of SEQ ID NO:1 or its reverse complement may additionally lack the proper arrangement of key nucleotide motifs required for tissue-specific promoter function. See, for example, Fiedler U. et al. (A complex ensemble of cis-regulatory elements controls the expression of a *Vicia faba* non-storage seed protein

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gene. Plant Mol Biol. 1993 Jul;22(4):669-79), who teach that an RY motif "CATGCATG" acts as a negative transcriptional regulatory element in the seed-associated promoter of the *Vicia faba* non-storage seed protein gene, and as a positive transcriptional regulatory element in seed-associated promoters obtained from other plant structural genes (page 677 paragraph spanning columns 1 and 2).

In the instant case Applicant has not provided sufficient guidance with respect to fragments or sequence variants of SEQ ID NO:1 or its reverse complement that retain the seed-preferred promoter functional properties of SEQ ID NO:1 and its reverse complement. Absent such guidance it would require undue experimentation for one skilled in the art to make and use fragments or sequence variants of SEQ ID NO:1 or its reverse complement that retain the seed-preferred promoter functional properties of SEQ ID NO:1 and its reverse complement, as one skilled in the art would have to isolate from undisclosed sources and/or synthesize fragments or sequence variants of SEQ ID NO:1 or its reverse complement, and then test each sequence for its ability to confer expression to a second polynucleotide in a plant seed in order to determine which fragments or sequence variants would function as claimed and which would not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 is indefinite in the recitation of "high stringency

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conditions". It is unclear what conditions would yield the claimed nucleic acid molecules because those skilled in the art define high stringency conditions differently. It is suggested that the claims be amended to recite specific hybridization conditions.


Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638


4/4/06

CC